REMARKS

Independent Claims 1-11 and 34-53 are canceled without prejudice to the filing of continuation and divisional applications. Claim 12 is amended to address that the polyurethane polymer has glass transition temperature property such that it can be directly melt blended with the at least one drug at less than about 150 °C even without an organic solvent. Support for the amendment can be found in the application, for example, on page 9, lines 11-15. Claim 16 has been amended to add a period that had been inadvertently omitted earlier. New claim 54 has been amended to address that there is no organic solvent without which the at least one drug cannot be directly melt blended with the polyurethane polymer at less than about 150 °C and that the reservoir is stable against phase separation of dissolved material. Support for the claim can be found in the application, for example, on page 4, lines 7-12. New independent claim 55 is added to address a device that has permeation enhancer and glass transition temperature property such that it can be directly melt blended at less than about 150 °C with the at least one drug even without an organic solvent and that the reservoir is stable against phase separation. New independent claim 56 is added to address a device similar to claim 55 but have further detailed features on the polymer and the permeation enhancer. Support for the new claims can be found throughout the application, including the above-cited lines for the above amendments. No new matter is added in the amendments and new claims. Claims 12-33 and 43-56 are pending.

Restriction

The Examiner imposed a restriction and withdrew from consideration claims 1-11 and 34-53. Applicants hereby affirm the election of Group II corresponding to claims 12-33 with traverse. The traverse is not on the ground that the two groups are obvious variants but on the ground that the Examiner can efficiently search them together.

35 USC §112 Rejection

The Examiner rejected claim 12 under §112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because in the claim the polyurethane polymer has a process temperature of less than about 150 °C but Example 1 showed this temperature is the temperature of melt blending. The rejection is respectfully traversed.

Applicants do not understand the rejection. The processing temperature in Example 1 is 65 °C (see page 18, line 26 of the specification). Thus, the process temperature is not 150 °C but significantly less than 150 °C. Further, even if assuming we gave an example with processing temperature of about 150 °C, that does not mean we cannot claim processing temperature of less than about 150 °C, since we clearly described a processing temperature of less than about 150 °C in the specification. The Examiner is requested to call the undersigned attorney if we misunderstood the example or relevant language to which the Examiner is referring.

35 USC §103 Rejection

The Examiner rejected claims 12-15, 20, 22 under 35 USC 103 as being unpatentable over US 6010715 ('715, Wick). Insofar as the rejection is maintained over the pending claims, Applicants respectfully traverse the rejection. Apparently the Examiner meant this rejection to be over Wick in view of Roreger US 5662923 ('923) because the Examiner referred to both '715 and '923 in the rejection.

It is noted that Wick does not disclose a device with polyurethane having a process temperature of less than 150 °C. For example, at the bottom of column 4 of Wick, the melt-blending temperature is between about 170 °C and 200 °C. There is no indication that the temperature can be lower. In fact, the Examiner admitted that Wick did not teach the temperature as claimed but referred to '923 as disclosing adhesive having processing temperature between 60 and 100 and that it would be obvious to melt blend the adhesive disclosed by '923. Applicants submit that the present invention is nonobvious over '715 even if combined with '923.

It is noted that '923 (Roreger) specifically included dexpanthenol in the melt blending. Dexpanthenol was used as a solvent for solubilizing the steroid hormones and preventing crystallization in the formulation (see Roreger, column 1, line 65 to column 2, line 20). Further the dexpanthenol has a highly softening effect, plasticizes the hot melt adhesive to reduce the softening temperatures so as to achieve the desired processing temperature (see Roreger, column 1, line 54-56 and Column 3, first paragraph). Thus, even though Roreger mentioned using processing temperature of between 60°C and 100°C, the processing was always done with

solvent, and particularly the addition of dexpanthenol. Thus, a powerful solvent/softener was used in melt blending the adhesive. Further, polyurethane was mentioned only in passing. There never was any teaching in '923 on how polyurethane can be melt blended with hormones, much less melt blending a polyurethane that can be melt blended with drug even without an organic solvent. Thus, there was never any teaching or suggestion or example that polyurethane could be processed even without any organic solvent. Since Roreger taught only that adhesive be processed with solvent, and that solvent could soften the adhesive, one skilled in the art would never be able to glean any insight on the ability to directly melt polyurethane with drug. In the present invention Applicants discovered that we could use polyurethane with the glass transition temperature property that enables direct melt blending polyurethane with drug even without organic solvent. Of course, organic solvents can be used if one chooses to. But the polyurethane was such that direct melt blending is possible even without organic solvent. This has never been taught or suggested by prior art.

The Examiner asserted that one would be motivated by the teaching of '923 that decreasing the melt temperature generally decreases the cohesive forces of the adhesive with reasonable expectation of having transdermal delivery device having a matrix of polyurethane with a processing temperature of between 60°C and 100°C. However, there would be no motivation to use a polyurethane that can have the relevant processing temperature range even without an organic solvent, since nobody ever mentioned such polyurethanes.

Thus, it is submitted that the amended claims and new claims are nonobvious over '715 and '923.

The Examiner also rejected claims 16-19 and 33 as being unpatentable over '715, in view of '923, and further in view of Re32991 (Szycher). Applicants respectfully traverse the rejection.

First, '991 is a wound dressing and entirely unrelated to transdermal drug delivery. Obviously a wound dressing is placed on a wound through which drug can pass. This is entirely different from a transdermal delivery system. In transdermal drug delivery, the drug has to pass

through the reservoir and through the body surface (such as skin). What works well for an open wound may fail miserably in transdermal delivery. Thus, the use a material for a wound dressing gives no suggestion or expectation of success for use of such in a transdermal delivery system. One skilled in the art will not combine '991 with '715 and '923.

Furthermore, even if assuming one would combine the three references, the deficiencies of the lack of motivation relating to melt blendability of the polyurethane even without organic solvent is not cured by '991. Therefore, the claimed invention is novel and nonobvious over '715, '923, and '991, either individually or in combination.

The Examiner also rejected claims 21, 23-29, 31-32 as being unpatentable over '715, in view of '923, and further in view of 6139866 (Chono). Applicants respectfully traverse the rejection. It is noted that Chono has nothing to do with polyurethane, much less polyurethane property related to processing temperature. Stability and drug permeation of the same drug (here in the cited claims being fentanyl) in different polymers can be very different. It is submitted none of the cited references would provide any motivation to combine Chono with the other two references. Moreover, even if assuming they can be combined, the result still will not cure the deficiency of the lack of mention of melt blendability of the polyurethane even without organic solvent.

The Examiner also rejected claim 30 as being unpatentable over '715, in view of '923, and '866 and further in view of 5225199 (Hidaka). Applicants respectfully traverse the rejection.

It is submitted that Hidaka also did not mention a processing temperature that is less than 150 °C. With the reasons similar to those stated above, Applicants submit that claim 30 is novel and nonobvious over the cited references.

CONCLUSION

Applicants believe that no fee is due with this communication. However, if it is determined that underpayment or overpayment has been made, the Director is authorized to debit or credit Deposit Account 10-0750, respectively.

Please direct any questions to the undersigned attorney at (650) 564-7054.

Respectfully submitted,

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